DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 23, 2014

LifeCell Corporation
Ms. Mira Leiwant
Director, Quality Engineering and Regulatory Affairs
One Millennium Way
Branchburg, New Jersey 08876

Re: K142326
Trade/Device Name: HPTM
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM and OXH
Dated: November 21, 2014
Received: November 24, 2014

Dear Ms. Leiwant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142326

Device Name
HPTM

Indications for Use *(Describe)*
HPTM is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes which require the use of reinforcing or bridging material to obtain the desired surgical outcome. The implant is intended for reinforcement of soft tissue in plastic and reconstructive surgery.

HPTM is intended for single patient, one-time use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K142326

I. SUBMITTER

LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876

Contact Person:
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Director, Quality Engineering and Regulatory Affairs
Phone: (908) 809-7747
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Prepared by and Date:
Keira Jessop
December 19, 2014

II. DEVICE

Name of Device: HP Tissue Matrix (HPTM)
Common or Usual Name: Surgical Mesh
Classification Name: Surgical Mesh—(21 C.F.R. §878.3300)
Device Class: II
Product Code: FTM and OXH

III. PREDICATE DEVICES

LTM-BPS Surgical Mesh (K082176)—LifeCell Corporation
This predicate has not been subject to a design-related recall

IV. DEVICE DESCRIPTION

HP Tissue Matrix is a surgical mesh that is derived from porcine dermis and is processed and preserved in a phosphate buffered aqueous solution containing matrix stabilizers. This device is designed to perform as a surgical mesh for soft tissue repair. The device consists of a terminally sterilized sheet of the processed porcine dermal matrix provided in prescribed geometric configurations and thicknesses and is packaged in a double pouch configuration. The device is considered a single use device which is to be used in a healthcare facility or hospital. It is sterilized via Gamma irradiation. The subject device has the same scientific technology, principles of operation, Intended Use, and Indications for Use as the cleared predicate device, LTM-BPS Surgical Mesh (K082176).

The changes described in this submission are the replacement and addition of solutions used during the processing of the LTM-BPS device.

V. INDICATIONS FOR USE

HPTM is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes which require the use of reinforcing or bridging material to obtain the desired surgical outcome. The implant is intended for reinforcement of soft tissue in plastic and reconstructive surgery.

HPTM is intended for single patient one-time use only.

VI. COMPARISON OF TECHNOLOGICAL CHARCTERISTICS WITH THE PREDICATE DEVICE

The subject and predicate devices are both surgical meshes that are derived from porcine dermis and then processed and preserved in a phosphate buffered aqueous solution containing matrix stabilizers. Both devices are designed to perform as a surgical mesh for soft tissue repair. Both devices consist of a terminally sterilized sheet of the processed porcine dermal matrix provided in prescribed geometric configurations and thicknesses and are packaged in a double pouch configuration. The subject device has the same scientific technology, principles of operation, Intended Use, and Indications for Use as the cleared predicate device, LTM-BPS Surgical Mesh (K082176).

The changes described in the submission are the replacement and addition of solutions used during the processing of the LTM-BPS device.

VII. PERFORMANCE DATA

Performance Data
Bench testing was performed on the subject HPTM device to support substantial equivalence. Testing included relevant elements of the FDA "*Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh"* Table 1 includes the applicable tests used to demonstrate substantial equivalence and applicable guidance documents or standard.

Table 1: Substantial Equivalence Testing Conducted

Test or Evaluation	**Applicable guidance document or FDA recognized consensus standard**
Mesh Thickness	N/A
Tensile Strength	N/A
Suture Pullout Strength	N/A
Tear Strength	ASTM D5735-95
Burst Strength	ASTM D6797-07(2011)
Device Stiffness	N/A
Biocompatibility	ISO 10993 -1, ISO 14971:2007
Drape	N/A

The results of the tests performed demonstrated that the modifications did not affect safety and efficacy of the device or raise any new questions of safety or efficacy.

Clinical Tests
No clinical testing was included in this submission.

VIII. **CONCLUSIONS**

The subject device, HPTM, meets the requirements to perform its intended use as a soft tissue patch and is substantially equivalent to the predicate device LTM-BPS Surgical Mesh (K082176).